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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/430,590	10/29/1999	RUSSELL TONY MASELL POULTER	674521-2001.	7513

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FROMMER LAWRENCE & HAUG
745 FIFTH AVENUE- 10TH FL.
NEW YORK, NY 10151

EXAMINER

LEFFERS JR, GERALD G

ART UNIT	PAPER NUMBER
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1636

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DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/430,590	POULTER ET AL.	
	Examiner	Art Unit	
	Gerald G Leffers Jr.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 7,8,15,16 and 22-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,9-14,17-21 and 33-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 October 1999 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>19,30</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

Receipt is acknowledged of an amendment to the claims, filed 3/12/02 as Paper No. 26. In Paper No. 26, several claims were amended (claims 1, 4-6, 9-10, 12, 17-19, 21) and new claims added (claims 33-34). A supplemental amendment was filed on 5/12/02 as Paper No. 27. In Paper No. 27 two new claims were added (claims 35-36). On 8/13/02 a supplemental response (Paper No. 29) was filed in response to a Notice of Non-Responsive Amendment (mailed 7/30/02 as Paper No. 28) wherein an accurate copy of the marked-up claims from the amendment filed in Paper No. 26 was provided to the examiner. This action is in response to Paper No. 29. Claims 1-36 are pending in the instant application with claims 7-8, 15-16, 22-32 withdrawn from consideration as being directed to non-elected inventions.

Receipt is also acknowledged of a Declaration from each of the inventors, filed 3/12/02 as Paper No. 25. In response to this declaration, a rejection of many of the claims under 35 U.S.C. 102(a) as being anticipated by Mathews et al is withdrawn. Any other rejection of record in the previous office action that is not addressed herein is withdrawn. This action is not final due to new grounds of rejection made herein that were not necessitated by applicants' amendment of the claims.

Drawings

This application has been filed with informal drawings that are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) or (b)(2) is granted permitting their use as formal

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drawings. In the event applicant wishes to use the drawings currently on file as formal drawings, a petition must be filed for acceptance of the photographs or color drawings as formal drawings. Any such petition must be accompanied by the appropriate fee as set forth in 37 CFR 1.17(i), three sets of drawings or photographs, as appropriate, and an amendment to the first paragraph of the brief description of the drawings section of the specification which states:

The file of this patent contains at least one drawing executed in color. Copies of this patent with color drawing(s) will be provided by the Patent and Trademark Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 14, 17-18, 33-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. ***This grounds of rejection is essentially the same as is made in Paper No. 24, mailed 9/13/01 and repeated below. It is extended to claims 14 and 17-18, and to new claims 33-36. A response to applicants' arguments follows the rejection.***

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Claims 1-6 are each drawn towards an isolated retrotransposon having a copy number of "between 40-150 or 50-100 copies" of itself per genome. The retrotransposon can be "free" or episomal, or the retrotransposon can be integrated. The retrotransposon can be isolated from fungi or yeast, or more specifically from *Candida albicans*. The broadest embodiments potentially encompass literally any eukaryotic cell type that might harbor a retro-transposable element (e.g. corn, yeast, human, fly, etc.). Even in more specific embodiments, the claims encompass any strain of *Candida* or, more specifically, *Candida albicans*. Each of the claims comprises the functional limitation of between 40 and 150 copies of itself per host cell genome.

The specification teaches one embodiment of the claimed invention (pCal or Tca2) which is found at high copy number in a few particular strains of *C. albicans*. No definitive explanation is provided in the specification for why pCal is maintained at such high copy number in these particular strains of *C. albicans* and not in others. For example, the mechanism could involve some mutation in pCal or a mutation in the particular host, or a combination of mutations in both the host and pCal. The prior art is of no help in describing a mechanistic rationale for maintenance of such high copy numbers because the art does not appear to teach such numbers.

Given the large number of host cell types and retrotransposable elements potentially embraced by the rejected claims and the presence of the functional limitation for high copy number, the presence of only a single relevant example in the specification or prior art meeting the functional limitation for high copy number and the lack of teachings from the specification or prior art as to how such a high copy number is attained by the single relevant example, one of skill in the art would not be able to envision a representative number of specific embodiments of the claimed invention to describe the potentially broad genus of such retrotransposable elements

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embraced by the rejected claims. Therefore, one of skill in the art would reasonably conclude applicants were not in possession of the claimed invention at the time of filing.

Response to Arguments

Applicants' have presented arguments against the above grounds of rejection in Papers No. 26 & 27. These responses essentially argue: 1) the invention is drawn to a novel retrotransposon, pCal, which is a member of the Ty1/copia group of retrotransposons, 2) data presented concerning the incidence of free and integrated copies of pCal, 3) the high copy number of the retrotransposon as free, linear dsDNA molecules is itself a characterizing feature of the claimed retrotransposons, 4) this feature is easy to determine experimentally, 5) the claimed retrotransposons have unique structural features (e.g. gag and pol reading frames are in phase and are separated by a single stop codon), 6) the 8 bp pseudo-knot is found in both the free and integrated pCal, 7) the four tandem repeats of GAAAAA are found in both the integrated and free forms of pCal, and pCal is the only known retrotransposon to have this feature, 8) the GAAAAA repeat is thought to act as a regulatory mechanism that produces more gag than gag-pol, and 9) a search of the NIH databases to determine the closest element to pCal/Tca2 has only 45% similarity to the protein encoded by pCal, and thus, pCal is extremely dissimilar to anything else in the database.

The assertion that the rejected claims are drawn only pCal is inaccurate. As was made clear in making the rejection, the claims read on a potentially extremely large genus of retrotransposons other than pCal. Those claims drawn to only pCal or Tca2 have not been rejected on these grounds. The data presented in Paper No. 26 concerning the relative frequency of pCal in *Candida* strains is not relevant for the above grounds of rejection as it does not provide

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a structural/functional basis for one of skill in the art to envision the nucleic acid sequence of other retrotransposons that must satisfy the functional limitations of the claims (i.e. maintain a specified number of free copies of itself per host cell). The assertion that it is easy to determine experimentally whether a giving retrotransposon is maintained at 40-150 copies per cell is better suited to a rejection for lack of enablement. The fact that the experimentation required to establish the functional limitation of 40-150 copies per cell may be routine does not provide a basis for one of skill in the art to envision what other retrotransposons will look like (i.e. envisioning their nucleic acid sequence, gene organization, etc.).

The assertion that the high copy number of free, non-integrated copies of the retrotransposon per cell is itself a distinguishing characteristic of the claimed retrotransposons is more an argument of a desired result rather than a distinguishing characteristic in the absence of a structural/functional basis for visualizing additional members of the broadly claimed genus. Such a basis for why pCal is maintained at such high frequencies in *Candida albicans* is not clear from the prior art and the instant specification. The several distinguishing characteristics described by applicants' response (i.e. tandem repeats, gag and pol in phase, 8 bp pseudo-knot, etc.) have not been directly linked to this recited functional limitation of the claims, nor is there reason to suppose that these characteristics are necessarily responsible for the functional limitation of maintaining 40-150 free copies per cell. In fact, the arguments concerning the unique nature of these distinguishing characteristics tend to support the instant rejection in that it points out how dissimilar pCal is from what has been described in the art and how hard it is to envision what other retrotransposons that are capable of meeting the functional limitations of the claims will look like (i.e. their nucleotide sequence). The rejection stands.

Claims 12, 14 and 19-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection, necessitated by applicants' amendment of the claims in Paper No. 26.**

The claims comprise the limitation of "...a nucleic acid that hybridizes under stringent conditions to the nucleotide sequence of (a)...". There is no literal support for this limitation in the instant application. Therefore, this limitation is impermissible NEW MATTER.

Claims 12, 14 and 19-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection.**

The rejected claims comprise the limitation of a "...nucleotide sequence with at least 65% similarity with the LTR and POL region SEQ ID NO: 3...". The rejected claims read on literally any retrotransposon or nucleic acid fragment that comprises a sequence with 65% similarity to SEQ ID NO: 3. This is an incredibly broad genus of retrotransposons and an even larger genus of nucleic acid fragments. The instant specification provides no basis for envisioning a representative number of embodiments of, for example, retrotransposons that are

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only similar at a 65% level with only part of the transposon sequence. The instant specification provides no basis for one of skill in the art to envision nucleic acid fragments that are only 65% similar to the LTR and POL regions of SEQ ID NO: 3 and which retain any sort of retrotransposon activity. As pCal appears to be novel in the art, the prior art does not offset the deficiencies of the instant specification with regard to providing a basis for envisioning a sufficient number of specific embodiments as to describe the broadly claimed genus. Therefore, one of skill in the art would have reasonably concluded applicants were not in possession of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-14 and 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is vague and indefinite in that metes and bounds of the phrase "...DNA transfer construct comprising.....(b) an integration factor..." are unclear. It appears from reading the specification that the construct would comprise a nucleic acid sequence which *encodes* the integration factor, which is a protein after all.

Claims 12 and 19 are vague and indefinite in that the metes and bounds of the phrase "...hybridizes under stringent conditions..." are unclear. The phrase is unclear in that the term "stringent hybridization conditions" is not clearly defined in the specification. The concept of what qualifies as "stringent" conditions is likely to vary from investigator to investigator, and is

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highly subjective. It would be remedial to amend the claim language to explicitly recite the "stringent" hybridization conditions (i.e. salt conditions, temperature, etc.).

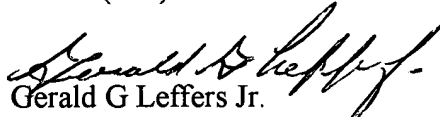
Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Gerald G Leffers Jr.
Examiner
Art Unit 1636

Ggl
June 15, 2003